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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 663,805	09 15 2000	Judith E. Kimble	960296.96650	3761

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QUARLES & BRADY LLP
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MILWAUKEE, WI 53202-4497

EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

15

DATE MAILED 06 06 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/663,805

Applicant(s)

KIMBLE ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12, 15-18 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12, 15-18 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9-15-00 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The amendment and response filed 3-26-03 have been received and entered.
2. Claims 10, 11, 13, 14, 19 and 20 have been cancelled.
3. Claims 1-9, 12, 15-18 and 21 are pending and under consideration in the instant application.
4. It is reiterated that the attempt to incorporate subject matter into this application by reference to Friedman et al Proc. Nat. Acad. Sci. USA 97:4736-4741, 2000 is improper because the reference was published in April 2000, almost seven months after the effective filing date of the instant application. Therefore, an artisan of skill would not have had access to the teachings of the reference at the time of the effective filing date of the claimed invention.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-9, 12, 15-18 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record set forth in the previous office action of 9-25-02.

Response to Arguments

Applicant's arguments filed 3-26-03 have been fully considered but they are not persuasive to obviate all the issues raised in the previous office action of 9-25-02.

Applicants' amendment of claims to recite *C.elegans* in place of a nematode are persuasive to withdraw the rejection regarding the issue of enablement pertaining to any nematode.

Regarding the issue: as to whether the *dpy* phenotype or embryonic lethal phenotype was specific to only PH4 gene, applicants argue that while there are other genes which would produce same phenotype, an artisan could determine which gene was responsible and such methods were known in the art. This indicates that such a step will be important for practicing the function. However, the method as instantly presented does not have any such step therefore, applicants' arguments do not address the issue adequately. Applicants' have indicated to Friedman et al PNAS paper, however, as noted in the previous office action, this article can not be used in support of the disclosure because it is a post filing art and its teachings were not available to the public at the filing of the instant application. Same arguments will be true regarding the issue of making a chimeric *C.elegans*? It is reiterated that the PNAS article is published in April 2000 was not available to an artisan at the time of the filing of the application.

Regarding the next issue of as to how a compound could increase the activity of P4H in a *C.elegans*, which had a mutated P4H gene, unless the effect of the mutation could be reversed by the compound, applicants did not address this issue. It is unclear as to how the lack of P4H activity due to a mutation could be reversed by treatment with a compound. Regarding claim 12, it is noted that this claim recites that a compound is into an animal that has a *dpy-18* phenotype or *poh-1* phenotype, however, if the phenotype is a dumpy phenotype, such a phenotype can be produced by mutation in several genes therefore, an artisan would not know whether rescue of the phenotype is due to rescued *dpy-18* activity or any other gene. Again, it is unclear as to how a compound can rescue the *dpy-18* or *poh-1* phenotype unless the compound can reverse the effect of the mutation in the genes.

Applicants' arguments regarding the issue of whether a human P4H gene or P4H gene of any other organism could rescue the P4H activity in a *dpy-18* or another mutant nematode are persuasive. However, applicants did not address the

issue regarding claim 9 that in view of the discussion that the dpy phenotype was not specific to P4H gene, it is not clear as to when a wild type nematode is treated with a test compound, how would an artisan know that the activity of P4H (dpy-18) on chromosome III was modulated and not that of any other gene such as dpy-2, dpy-10, sqt-1, dpy-13 and rol-6.

In conclusion, the specification does not provide sufficient guidance as to how an artisan of skill would have made the claimed invention in view of the issues raised above. An artisan of skill would have required extensive experimentation to address the issues raised above and such experimentation would have been undue since such experimentation was not routine in the art and the specification does not provide necessary guidance how to address the issues raised above.

7. The 112 second paragraph rejection of claims 1, 3, 8, 12, and 17 has been withdrawn in view of applicants' arguments and amendments.

8. No claim is allowed.

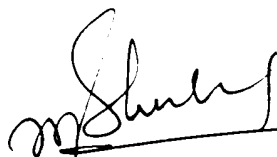
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is

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(703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. The after-final fax number is (703) 87209307. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

A handwritten signature in black ink, appearing to read 'R. Shukla', is written over a horizontal line.

RAM SHUKLA
PRIMARY EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632